510(k) Summary

Date Prepared:	June 20, 2013
Contact:	John Kuczynski, VP R&D and RA Medyssey USA Inc. 1550 E. Higgins Road Suite 123 Skokie, IL 60077 847-427-0200 888-518-9070 (fax)
Trade Names:	Iliad Pedicle Screw System Kora Pedicle Screw System Zenius Pedicle Screw System
Product Class:	Class III
Classification:	21 CFR §888.3070 Pedicle Screw Spinal System
Common Name:	Pedicle Screw System
Product Codes:	MNI, MNH, NKB
Panel Code:	87

AUG 2 3 2013

Purpose:
The purpose of this Premarket Notification is to add sizes of components to these three previously cleared pedicle screw systems and to change the indications for use for all systems to be consistent with the NKB (Class III) indications for pedicle screw systems.

Indications for Use:
The Medyssey Co, Ltd. Zenius, Iliad and Kora Spinal Systems are intended for posterior, noncervical pedicle fixation as an adjunct to fusion in skeletally mature patients using autograft and/or allograft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation): spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Device Descriptions:

The **Iliad**^{TM} Spinal Fixation and Adjustable Bridge System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients.

The **Kora**^{TM} Spinal Fixation and Adjustable Bridge System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants

are available so that adaptations can be utilized to take into account the unique pathology of individual patients.

The **Zenius™** Spinal System, Internal Fixation Device for Spinal Surgery is comprised of: Rods, Pedicle Screw Assemblies, Compression Retaining Assemblies, and Transverse-Link Assemblies. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology of individual patients.

For all three systems, components are manufactured from Ti6Al4V ELI per ASTM F136 and wrought Co-Cr-Mo alloy per ASTM F1537.

Predicate Device(s):
The Medyssey Pedicle Screw Systems are substantially equivalent to the Zenius, Iliad and Kora pedicle screw systems found in K121670, K110283 and K110284.

Performance Standards:
The additional components being added in this submission do not represent a new worst case. Therefore, no new performance testing is necessary to justify their substantial equivalence. Static and dynamic compression bending, static torsion and per ASTM F1717 was performed on the predicate worst constructs and presented in the predicate submissions.

Conclusion:
Medyssey concludes that these Pedicle Screw Systems are substantially equivalent to the predicate Pedicle Screw Systems with the same names and raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 23, 2013

Medyssey USA, Incorporated
% Rich Jansen, Pharm.D.
Silver Pine Consulting, LLC
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K131878
Trade/Device Name: Iliad, Kora and Zenius Spinal Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: June 25, 2013
Received: June 27, 2013

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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Prescription Use ___V____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131878